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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,132	02/28/2002	Haiyin He	ACY-33,316-D3	3248
25291	7590	12/03/2003	EXAMINER	
WYETH PATENT LAW GROUP FIVE GIRALDA FARMS MADISON, NJ 07940			RILEY, JEZIA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,132	HE ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,8-12,29-33,39-43,55,56,60 and 62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-6,8-12,29-33,39-43,55,56,60 and 62 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6, 8, 9-12, 29-33, 39-43, 55, 56, 60, and 62 are rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for the chemotherapeutic agents disclosed in the instant claims 3, 5, or 55 for example, does not reasonably provide enablement for the employment of any chemotherapeutic agents and any chemosensitizing reversal agents employed in the instant rejected claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In Re Colianni*, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board Appeals and Interferences in *Ex Parte Forman*, USPQ 546 (BPAI 1986).

Among these factors are: the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the breadth of the claims, the amount of direction or guidance present, and the presence or absence of working examples.

The claims are broadly drawn to a method for non P-gp/non MRP multiple drug resistant cancer cells comprising administration of an effective amount of a chemosensitizing reversal agent and a chemotherapeutic agent.

A broad possible range of chemotherapeutic agents and chemosensitizing reversal agents are possible and it is undue experimentation to enable the selection of useful chemotherapeutic agents and chemosensitizing reversal agent needed. Functional language at the point of novelty herein employed by applicants is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997). The CAFC clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, require a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405, and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus.." at 1406.

In the instant application, "a chemotherapeutic agent" and a "chemosensitizing reversal agent", recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited

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functions. Thus the instant claims fail to meet the requirements set forth under 35 U.S.C. 112, first paragraph.

The specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant rejected claims.

Therefore given the unpredictability of the art and the lack of guidance in the specification, it is the Examiner's position that one skilled in the art could not perform the method of the claims as broadly recited without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4-6, 8-10, 29-31, 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Abe et al. (British Journal of Cancer , 1995, 72, pages 418-423).

Abe et al. discloses method of determining the chemosensitization of spontaneous multidrug resistance in human cancer cells exhibiting such resistance comprising administering an effective amount of chemosensitizing reversal agent such

as verapamil in combination with a chemotherapeutic agent such as doxorubicin (page 418 and 421-422).

Claims 2, 4-6, 8-10, 29-31, 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenberger et al (Oncology Research, Vol. 8, No. 5, pp. 207-218, 1996).

Greenberger et al. discloses chemosensitizing agent that restored sensitivity to drugs in the multidrug resistance (MRD) phenotype in cell lines that overexpress P-glycoprotein. Such agents resensitized drug-resistant tumors to vinblastine or doxorubicin in an ascitic or solid tumor model respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Wednesday, November 26, 2003


JEZIA RILEY
PRIMARY EXAMINER